FACTSHEET

NTP CENTER FOR PHOTOTOXICOLOGY

FDA-NIEHS Phototoxicology Research and Testing Laboratory

Year 2001

National Toxicology Program

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NATIONAL INSTITUTE OF ENVIRONMENTAL HEALTH SCIENCES

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The FDA-NIEHS Phototoxicology Research and Testing Laboratory is now operational and has been designated the NTP Center for Phototoxicology. Many types of compounds including cosmetic ingredients, sun block chemicals, tanning enhancers, skin colorants, and tattoo inks can be studied with regard to their effects on UV radiation or simulated solar light-induced toxicity and cancer in laboratory animals. The exposure of U.S. citizens to UV radiation or sunlight is increasing through more frequent use of tanning booths to augment skin coloration and the trend toward spending increasing amounts of leisure/pleasure time in sunlight-oriented activities (e.g., beach, swimming pools). Research and testing activities at the NTP Center for Phototoxicology should have a significant impact on the quality and timeliness of information available for public health decisions concerning the safe use of products on sun exposed skin.

The FDA has had an ongoing interest in phototoxicity and photocarcinogenicity of therapeutics, cosmetics, devices and food supplements/additives, and recently developed an intra-agency photobiology research program. The NIEHS has developed an intramural photobiology research program, and concurrently, the National Toxicology Program (NTP) has reviewed the nominations of drugs/chemicals that required phototoxicology testing as part of the overall safety assessment. The NTP Center for Phototoxicology was envisioned as a mechanism to facilitate some of the research and testing needs of the FDA, NIEHS, and NTP. The laboratory is located at the FDA's National Center for Toxicological Research in Jefferson, Arkansas. Solar light is simulated in the animal facilities using 6.5 kWatt xenon-arc lights. The transmitted light is attenuated using quartz filters to achieve a spectrum that closely mimics terrestrial solar light. The facility is also capable of exposing mice to many different types of fluorescent tube generated light, including the widely used UVB emitting FS lamps or suntan-bed lamps. Photocarcinogenicity studies will use the SKH-1 hairless mouse as the primary test animal, and as appropriate, additional test animals (e.g. transgenic mice) will be used. A standing committee (Toxicology Study Selection and Review Committee) reviews experimental protocols and progress of studies.

Interest in developing a jointly operated phototoxicology research and testing laboratory was heightened with FDA's nomination of alpha-hydroxy acids to the NTP. These compounds are primarily used as dermatological chemoexfoliants. Use of alpha-hydroxy acid-containing cosmetics is increasing as the beauty-conscious public seeks drugs or cosmetic preparations that will give a more youthful appearance. Two possible consequences of chemoexfoliation are increased proliferation of epidermal epithelial cells and deeper penetration of electromagnetic radiation into the skin. In light of these changes, the impact of continuous use of this type of treatment on the incidence of sunlight-induced skin cancer is not known. Studies are now underway at the Center to allow quantitative determination of the effect of alpha-hydroxy acid treatment on the induction of mouse skin cancer (SKH-1 hairless mouse) by simulated solar light.

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